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Tension-free vaginal tape-obturator and tension-free vaginal tape-Secur for the treatment of stress urinary incontinence: a 5-year follow-up randomized study

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ABSTRACT

Objective: Single-incision slings were developed to overcome the complications related to retropubic and trans-obturator tapes. TVT-Secur was the first of this kind of devices to be marketed and yielded contrasting results. Aim of this non-inferiority study is to report the 5-year follow-up of a randomized, single-blind, controlled trial comparing TVT-O to TVT-Secur.

Study design: Randomized, single blind, controlled study conducted in two tertiary urogynecological centers. 154 patients were allocated to either TVT-O or TVT-Secur and were contacted 5 years after the procedure to undergo urogynecological examination (POP-Q staging, challenge stress test and post-void residual urine evaluation), to complete I-QOL and PGI-I questionnaires, and to score their satisfaction on a 5-point Likert scale. Patients who were not objectively evaluated were interviewed over the telephone. Primary outcome was subjective success defined as being "very much improved" or "much improved" on the PGI-I.

Results: 120 patients were evaluated only subjectively (TVT-O: 62; TVT-Secur: 58) and 84 objectively and subjectively (TVT-O: 46; TVT-Secur: 38). Subjective success (79% vs. 63.8%) and objective cure rates (82.6% vs. 68.4%) 5 years after the procedure were lower for TVT-Secur, but not significantly. Recurrent UTIs were reported by 17.8% of women (TVT-O 9, TVT-Secur 6) and two de novo urgency cases (one per group) were observed. Re-operation rate for stress urinary incontinence (SUI) was 20%.

Conclusions: TVT-Secur did not show an inferior subjective success rate in comparison with TVT-O five year after the original procedure, even though displaying a clear trend toward a lower efficacy. Considering that the long-term safety profile is similar between the two procedures, there are no advantages in using TVT-Secur.

Introduction

Complications related to retropubic (organ and vascular injuries) and trans-obturator (persistent groin/thigh pain, dyspareunia) tapes [1,2] prompted the industry to market single-incision devices, whose aim was to avoid the blind passage either through the Retzius space or the trans-obturator canal, thus reducing the risk of lesion to solid organs, vessels, and nerves.

The first kind of these minimally invasive devices to be marketed was TVT-Secur, an 8-cm long, laser-cut polypropylene mesh, which is positioned with a retropubic or hammock approach by a single vaginal incision and has self-attaching ends to the internal obturator muscle or its surrounding structures [3]. This device seems to cause less post-operative pain and to reduce operative time [4,5], but its effectiveness seems to be lower in comparison with traditional mid-urethral slings (MUS) [4,5]. However, a number of studies reported satisfying results, also at mid-term [6–9].

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Criticisms have been made regarding the anchoring mechanism of TVT-Secur, with studies demonstrating a deterioration in time of the efficacy of this single-incision slings calling for long-term studies in the field of surgical treatment of SUI [10,11]. Following these contrasting results, this device was withdrawn from the market. We designed and implemented a single-blind, randomized trial comparing tension-free vaginal tape-obturator (TVT-O) with TVT-Secur (hammock approach) and demonstrated that the latter was not inferior to the established trans-obturator tape, 36 months after the original procedure [6].

The aim of the present report is to compare the long-term efficacy and safety of these two devices, hypothesizing that TVT-Secur is not inferior to TVT-O five years after the procedures.

Methods

This was a single-blind, randomized study performed in two Urogynecological Units following approval by the Institutional Review Boards of our Institutions, and after all patients gave informed consent to participate in the study. As described in the original report of this study [6], from April 2008 to April 2009, 238 patients affected by urodynamic SUI and candidate for a mid-urethral sling procedure were evaluated for inclusion in the study. A detailed description of the methods was previously published, including surgical procedures, inclusion and exclusion criteria, and pre-operative evaluation [6]. In particular, inclusion criteria were: SUI as diagnosed by clinical evaluation and urodynamics, age >30 years, and previously failed pelvic floor muscle training; while exclusion criteria were: previous surgery for SUI, isolated overactive bladder symptoms, pelvic organ prolapse ≥POP-Q stage II, neurologic disease, and serious contra-indications to surgical procedures.

In total, 154 patients were randomized in a 1:1 ratio by means of a randomization list generated by a computer with blocks of 6 to undergo either TVT-O or TVT-Secur hammock approach (Ethicon Gynecare, Somerville, NJ, USA). Patients were blinded to the procedure until the 12 month follow-up visit. The single blind

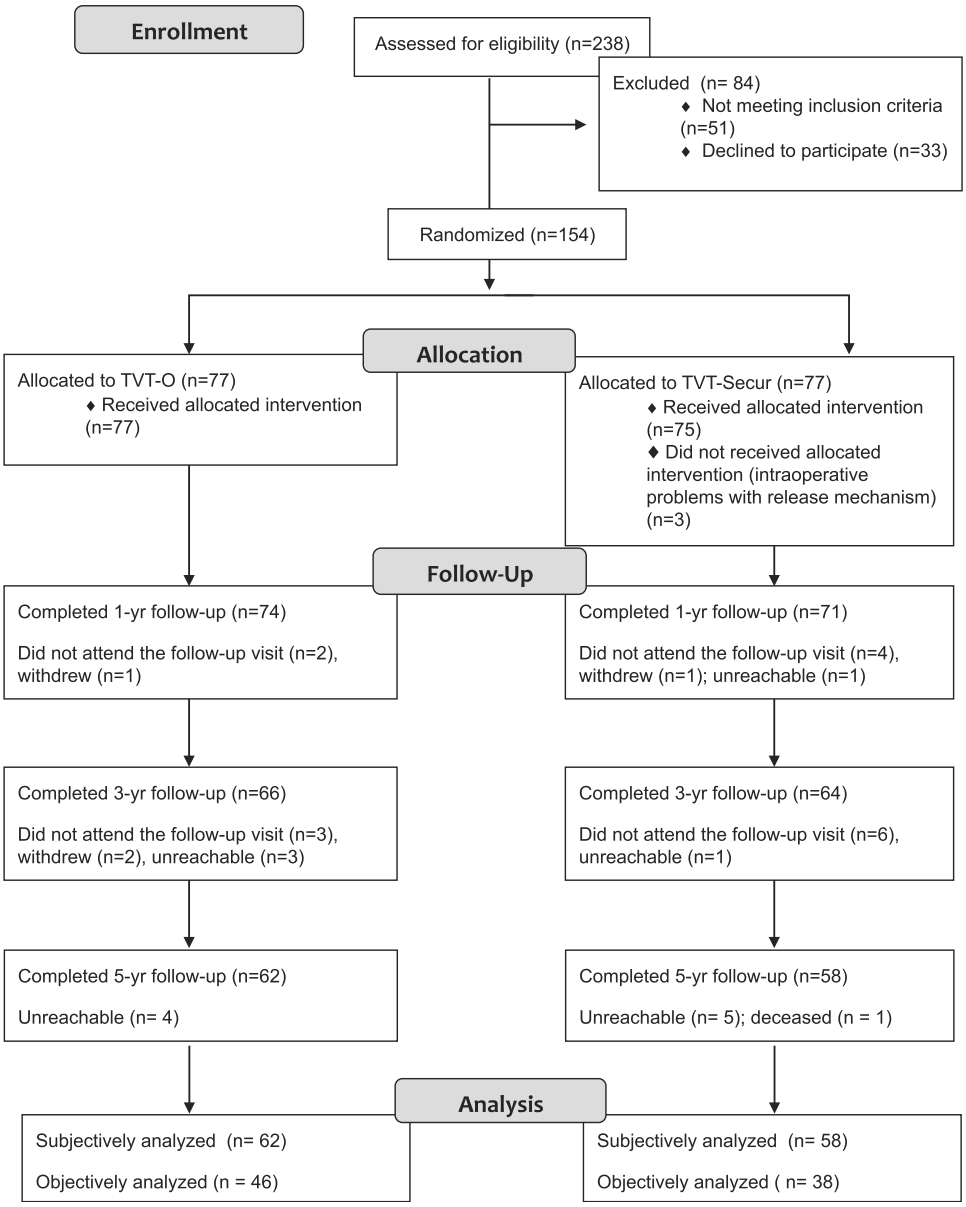

Fig. 1. Consolidated standards of reporting trials flowchart of patient recruitment and follow-up.

Table 1
Characteristics of the subjects studied. Values are given as mean ± SD, unless otherwise specified.

	TVT-O (n = 77)	TVT-Secur (n = 77)
Age (years)	60.4 ± 8.4	56.9 ± 7.2
BMI (kg/m^2)	28.8 ± 6.0	27.1 ± 2.9
Menopausal status, n (%)	65 (84.4)	66 (85.7)
Parity (median [range])	2 [0–4]	2 [0–3]
Q-tip test (°)	64.3 ± 11.5	50.3 ± 14.1
VLPP (cmH_2O)	92.3 ± 13.0	94.5 ± 11.3
Qmax (ml/s)	33.1 ± 15.3	28.8 ± 12.6
Voided volume (ml)	345 ± 128	358 ± 157
Post voidal volume (ml)	31 ± 17.2	36 ± 14.5

study design was adopted to reduce bias derived from the patient's knowledge of which procedure she underwent.

The initial cohort included 154 women (Fig. 1). We choose a non-inferiority study design [12] for the evaluation of the primary end-point on the basis of a previous randomized study comparing TVT-O with TVT-Secur with a 12-month follow-up [13]. Assuming that approximately 110 patients (71%; 55 for each arm) would respond 5 years after the procedure and a success rate for the TVT-O of 83% [14], this would allow us to have a 70% power to detect a 20% difference in the patient-reported success rates between the two groups. Women who received further continence surgery (n = 10) in the first 36 months from the original procedure were included in this follow-up study, but regarded as failures.

The 154 women included in the original cohort were contacted by telephone between January and April 2014 (i.e. after a minimum of 5 years follow-up) and invited at our Institutions to undergo a complete urogynecological examination by an independent assessor. The evaluation included POP-Q staging, challenge stress testing (CST) with 250-mL bladder filling, and post-void residual urine (PVR) evaluation. Patients also completed the Incontinence-Quality of Life (I-QOL) questionnaire [15] and the Patient Global Impression of Improvement (PGI-S) questionnaire [16]. Patients were also questioned regarding any further treatment they might have received for recurrent SUI, and the occurrence of any complication. They also answered to the question: "are you satisfied with the procedure?" using a 5-point Likert scale (1 – strongly disagree; 2 – disagree; 3 – neither agree nor disagree; 4 – agree; 5 – strongly agree). Patients who refused to attend the examination, or those who did not attend the scheduled examination, were interviewed over the telephone by a blinded assessor.

The primary outcome measure at 5 years was the patient-reported success rate defined as "very much improved/much improved" on the PGI-I. Other responses were considered as failures. Secondary outcomes were objective cure rate (defined as a negative CST), patient satisfaction (defined as a score ≥4 on the Likert scale), improvement in quality of life (defined as a ≥20 point increase on the total I-QOL score), re-operation rate, and late complications (onset after >36 months).

Statistical analysis was performed using the Statistical Package for Social Science, version 17.0 (SPSS, Chicago, IL). Data distribution for continuous variables was assessed with the Shapiro–Wilk's test. Student's t test for paired and unpaired samples was used to compare parametric variables between and within groups, respectively. The Mann–Whitney and the Wilcoxon tests were used to analyze difference in non parametric parameters between and within groups, respectively. The efficacy was analyzed using the non-inferiority unilateral u test, as reported elsewhere [12]. Differences in proportions between groups for secondary outcomes were analyzed with the χ^2 test. Statistical significance was set for a p value of <0.05.

Results

One-hundred and twenty of the 154 women originally included in the study (78%) (TVT-O: 62; TVT-Secur: 58) were evaluated subjectively. Moreover, a subset of 84 (54.5% of the original cohort) also underwent objective evaluation (TVT-O: 46; TVT-Secur: 38). Fig. 1 reports a CONSORT flow-chart of the study. Median follow-up was 63 months (range 60–72) for TVT-O and 65 for TVT-Secur (range 60–72).

Baseline characteristics of the patients included in the study are reported in Table 1. No significant differences were observed between groups.

In the per-protocol analysis, no statistical differences were observed in the success rates of the two groups five years after the procedure (Table 2). Forty-nine women (79.0%) in the TVT-O group and 37 (63.8%) in the TVT-Secur group (p = .04; RR 1.239, 95% CI 0.965–1.561) reported to be either "very much improved" or "much improved" on the PGI-I. There was no significant decline in cure rates over the follow-up period in both groups, but TVT-Secur showed a higher reduction in comparison with TVT-O (75% to 64% vs. 80% vs. 79%). Different analysis dealing with dropouts were carried out (missed value considered as failure and missed value considered cured) (Table 2). Intention-to-treat analysis showed a lower success rate for TVT-Secur that nearly reached statistical significance (63.6% vs. 48.1%; p = 0.049).

No statistical differences were observed in the proportion of patients with negative CST (82.6% vs. 68.4%; p = 0.2), with an

Table 2
Patient-reported success rates and ITT analysis dealing with dropouts.

	Success (n [%])		RR (95%CI)	P^*
	TVT-O	TVT-Secur		
PGI-I (n = 120)	49 (79.0%)	37 (63.8%)	1.239 (0.965–1.561)	0.040
Assuming all missing data are failures (n = 154)	49 (63.6%)	37 (48.1%)	1.324 (0.975–1.792)	0.049
Assuming all missing data are cured (n = 154)	64 (83.1%)	56 (72.7%)	1.143 (0.950–1.792)	0.008

* Non-inferiority test
CI: confidence interval

Table 3
Secondary efficacy outcomes.

	Success (n [%])		RR (95%CI)	P
	TVT-O	TVT-Secur		
Negative CST (n = 84)	38 (82.6%)	26 (68.4%)	1.201 (0.922–1.543)	0.2
I-QoL (n = 120)	52 (83.9%)	42 (72.4%)	1.158 (0.940–1.596)	0.1
Satisfaction score (n = 120)	64 (83.1%)	56 (72.7%)	1.143 (0.950–1.792)	0.4

increase of ≥20 on the total I-QoL score (83.9% vs. 72.4%; $p = 0.1$), and with a satisfaction score ≥4 (72.6% vs. 65.5%; $p = 0.4$) between the two groups (Table 3).

None of the women reported either persistent or newly onset thigh or groin pain. No new vaginal extrusion or urethral/bladder erosion were seen in the 84 patients who underwent objective evaluation, and no woman interviewed by telephone reported symptoms that might be ascribed to vaginal extrusion (foul vaginal discharge, dyspareunia). Recurrent UTIs (more than 3 episodes/year) were observed in 15 (17.8%) women (9 in the TVT-O group and 6 in the TVT-Secur group) and managed with antibiotics. One of these women (undergone TVT-O) developed grade III cystocele, but refused surgical correction. Of the six patients reporting de novo urgency at the 36 month follow-up (2 in the TVT-O group and 4 in the TVT-Secur group), four were on anticholinergic drugs while two stopped drug therapy and did not report any symptoms. Two more patients (one per group) reported de novo urgency after the 36 months follow-up and were treated with β3-adrenergic drug. Mean PVR was 27.0 ± 21.9 ml for TVT-O and 23.5 ± 16 ml for TVT-Secur ($p = 0.6$). Only one woman in the TVT-O group showed a PVT > 100 ml and was the woman with grade III cystocele and recurrent UTI.

Twenty-four women (20%) underwent further surgical treatment for recurrent SUI. In the first three years, 10 women requested repeated anti-incontinence surgery (4 in the TVT-O group and 6 in the TVT-Secur group), while 14 more women underwent a second surgical treatment (5 in the TVT-O group and 9 in the TVT-Secur group) after the 36 months follow-up. During the whole follow-up period, 15 women in the TVT-Secur group and 9 in the TVT-O group underwent a second anti-incontinence procedure. All women who had TVT-Secur as the primary procedure underwent TVT-O, while 7 women in the TVT-O group underwent retropubic TVT and 2 repeated TVT-O. Of the 20 women requiring repeat surgery, 18 were objectively cured (90%), while two (10%) reported persistent SUI and underwent bulking agent injection with a significant improvement of SUI symptoms.

Comment

Even though a number of randomized studies report on mid-term efficacy of TVT-Secur, some reporting good outcomes [6–9], other indicating a high failure rate [10,18–20], to our knowledge this is the first to report a 5 year follow-up. Meta-analysis of studies evaluating short and medium-term efficacy of TVT-Secur show a lower efficacy of this single-incision sling in comparison with traditional MUS [4,5].

The efficacy five years after the original procedure is not inferior to TVT-O in the surgical treatment of female SUI. Nevertheless, long-term subjective success rate of TVT-Secur, as defined by PGI-I, seems to be lower than TVT-O, although not significantly, in particular for intention-to-treat analysis. In comparison with the 36 month follow-up, TVT-Secur showed a higher reduction of subjective outcomes than TVT-O. These data seem to indicate that, even though not significantly, subjective effectiveness of TVT-Secur decreases over time more than that of TVT-O. Indeed, a limitation of our study is the sample size of 120 patients, based on a power calculation of 70%, to show a 20% difference in success or complication rates. Power of 70% assumes a 30% chance of a type II (beta) error. This presents an unusually high chance of falsely accepting the null hypothesis that there is no difference between the two sling interventions. With a higher power calculation, and hence a larger sample size, the study may well have demonstrated a difference in outcomes between the two procedures. All efforts were made to contact all patients included in the original cohort in order to either visit them at our Institutions or to interview them over the phone. We managed to have a response rate of 78%, which is in line with other studies or slightly higher [21,22]. However, due to the small number of the original cohort we missed to have an 80% power for this long-term analysis. All these consideration taken together, in particular the clinical relevance of the decline of the subjective efficacy of TVT-Secur, and the limited advantages of this device in the long-term, suggest us that TVT-O may be a better choice.

Objective cure rate (in a subset of patient), long-term impact on quality of life and patients' satisfaction do not seem to be different between the two procedures. This discrepancy may be explained by the fact that objective evaluation may not reflect the normal daily activities and, thus, underestimate the incidence of recurrent SUI and that long-term quality of life might not uniquely be influenced by the anti-incontinence procedure. Overall, both procedures received a fair satisfaction score by patients, indicating a similar impact in their global opinion.

Regarding the differences with other studies reporting a significant lower medium-term efficacy of TVT-Secur [10,17–20], it must be said that also short-term follow-up showed unsatisfying results, while randomized trial reporting favorable outcomes in the short-term confirmed these results on the medium-term [6,7,9,13]. Thus, it can be hypothesized that two kind of recurrences exist for TVT-Secur: short-term failures, mainly linked to an incorrect positioning or early failure of the sling and identified both at short- and long-term, and long-term recurrences, probably due to insufficiency of the tape in avoiding SUI. This seems to be reflected by the re-operation rate. There were no difference in re-operation rate between the 3-year and the 5-year follow-up for TVT-Secur, but 5 patients were re-operated in the first 6 months from the original procedure, and only one up to 36 months. After that, 9 more patients in the TVT-Secur group were re-operated on, all between 4 and 5 years after the original procedure. Re-operations for TVT-O were more homogeneously scattered throughout the period of follow-up.

Long-term safety profile of both devices seems to be favorable. Indeed, no new cases of vaginal exposure or persistent or chronic groin/thigh pain was observed in either groups. This results is consistent with other medium-term studies on TVT-O, showing virtually no cases of chronic pain [9,14,23–25]. Considering that TVT-Secur was developed primarily to reduce persistent pain, it is clear that, in the long-term, this seems not to be an advantage. In our previous study [6], TVT-Secur showed a somewhat higher incidence of de novo urgency. In this follow-up, no differences were observed in the number of new de novo urgency cases between TVT-O and TVT-Secur, so that the initial difference might be ascribed to the tensioning difficulties related to TVT-Secur.

This study has a number of limitations. Apart from the limited power of the study, only a subset of women was objectively evaluated and this might have induced the differences observed in the objective cure rate and the subjective success. Moreover, the study was a dual center study, so it may lack external validation. Another limitation is that women not presenting for the examination were interviewed over the phone and that questionnaires were not mailed to them. This might have introduced some sort of bias on the basis of the attitude of the interviewer. We tried to limit the bias asking a blinded assessor to perform the interview and we preferred the direct telephone contact because we felt that the mailing process would have induced a higher non-responders rate.

Strengths of this study rely on its randomized design, with robust exclusion and inclusion criteria and use of validated tools for objective and subjective evaluation. Moreover, both objective and subjective evaluation were performed by blinded observers. Another strength is that objective data were obtained in a significant proportion of participants, which is particularly difficult in case of long follow-ups.

In conclusion, TVT-Secur did not show an inferior subjective success rate in comparison with TVT-O five year after the original procedure, even though displaying a trend toward a lower efficacy. On the other hand, considering that the long-term safety profile is similar between the two procedures, there are no advantages in using the single-incision sling TVT-Secur for the management of SUI. Thus, our data support the withdrawal of this device from the market. TVT-O showed a persistent efficacy over a period of 5 years and a high safety profile.

Disclosure

G.A. Tommaselli is consultant for Ethicon and Solace Therapeutics; A. D'Afiero is consultant for AMS; all other authors state that they have no conflict of interest.

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